(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 November 2001 (22.11.2001)

PCT

(10) International Publication Number
WO 01/87079 A1

(51) International Patent Classification[7]: A23D 9/05, A23L 1/30, 1/302, 1/304

(21) International Application Number: PCT/DK01/00296

(22) International Filing Date: 1 May 2001 (01.05.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
00201749.9 18 May 2000 (18.05.2000) EP

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/87079 A1

(54) Title: A NUTRITIONAL COMPOSITION FOR DIETARY SUPPLEMENTS

(57) Abstract: By the present invention, a nutritional composition is provided for use as a nutritional supplement to a diet on a regular basis, e.g. on a daily basis. The composition comprises vitamin compounds comprising a selection of vitamins, mineral compounds comprising a selection of minerals, and fish oil granulate in dry pulverised form comprising eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Hereby, a comprehensive nutritional supplement is provided by which the diet may be supplemented not only by minerals and vitamins but also by the omega-3 fatty acids EPA and DHA of the fish oil granulate. Side effects such as bad taste and smell are removed by using the fish oil granulate.

A NUTRITIONAL COMPOSITION FOR DIETARY SUPPLEMENTS

The present invention relates to a nutritional composition for use as a dietary supplement.

It is widely acknowledged to enrich the daily diet with a nutritional supplement such as one or more tablets containing a selection of vitamins and minerals. The daily amount of tablets is chosen so that the vitamin and mineral contents of the tablets correspond to recommended daily amounts.

In addition to the vitamin and mineral supplements, nutrition experts often recommend to supplement the diet with fish oil, in particular if seafood is vacant from the diet. It is recognised that people, such as Eskimos, who consume large quantities of fish and other seafood products rich in these oils have a far lower risk than most other populations of suffering from various heart and circulatory disorders, which are among the major killers of our time.

The active ingredients in the fish oil are polyunsaturated fatty acids with chains of 18, 20 or 22 carbon atoms with 2-6 double bonds. There are two kinds: n-3 omega and n-6 omega fatty acids. These acids are essential and the human body needs them but cannot produce them. Thus, they must be supplied in the diet. The n-6 omega fatty acid is found in many vegetable oils and other oil products.

However, the omega-3 acids EPA and DHA are only found in fish and other marine life. The fish oil is therefore the most important food source for the omega-3 fatty acids.

In order to receive the required amount of fish oil every day, fish oil in liquid form may be taken besides the vitamin and mineral pills. The liquid fish oil may preferably be taken in a capsule form. However, some people who supplement several grams of fish oil each day will experience gastrointestinal upset and burp up

a "fishy" smell even hours after the fish oil is taken. Many people may therefore refrain from supplementing their diet with fish oil capsules.

Other drawbacks of vitamin and mineral pills and fish oil capsules are that several pills and capsules must be taken each day. Capsules of highly concentrated fish oil are produced in order to reduce the volume, and in turn reduce the daily number of capsules required.

EP-A-0 276 772 describes a process for preparing a microdispersed, pulverulent or aqueous fish oil preparation with a high concentration of the active substances of the fish oil, in particular EPA and DHA. This preparation of fish oil may result in a reduction of the bad smell and taste of fish oil and is used in baby food and dry-powdered milk as well as supplements in bakery and other nutritional food products.

However, in order to get a complete nutritional supplement, a person must eat both vitamin pills and a number of capsules. Together with the drawbacks involved in supplementing the diet with fish oil, this causes many people to refrain from supplementing their diet with nutritional supplement, and it is therefore the object of the invention to provide a nutritional composition that overcomes the above-identified drawbacks of the conventional diet supplements.

This object is achieved by a nutritional composition for dietary supplements containing (a) a vitamin portion including a selection of vitamins and derivatives thereof selected from a group of: β-carotene, vitamin B_1, vitamin B_2, vitamin B_3, vitamin B_5, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D_3, vitamin E, folic acid and biotin, (b) a mineral portion selected from a group comprising compounds of calcium, magnesium, zinc, iron, iodine, selenium and chrome, and (c) at least 50 % by weight fish oil granulate containing polyunsaturated fatty acids including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

By the present invention, a comprehensive nutritional composition supplement is provided where all daily nutritional supplements may be provided within a single

composition, e.g. a tablet. In the fish oil granulate, a high concentration of EPA and DHA is present. Thus, the amount of fat calories are reduced in comparison with the fish oil liquid. This means that the calorie consumption in connection with the fish oil diet supplement may be reduced.

By using a microdispersed fish oil preparation in a granulate form, the "fishy" smell is eliminated. Moreover, the active substances EPA and DHA are provided in a highly concentrated form. By the invention, it is realised that this pulverised fish oil preparation may be incorporated in a comprehensive nutritional supplement in the form of a tablet.

A composition according to the invention comprises, besides EPA and DHA, a collection of vitamins and minerals. The vitamins are selected from a group of vitamins in suitable amounts that are chosen in correspondence with the recommended daily intake amount of each of the particular vitamin substances. Similarly, the minerals are chosen in accordance with the recommended daily amounts (RDA) set by nutrition experts and national nutritional and/or health authorities.

By the invention, it is realised that the nutritional composition may be designed specifically to different human requirements, such as that of children, pregnant women, young people, elderly people, etc. Moreover, it is realised that the nutritional composition may be specifically designed in accordance with specific geographic and/or cultural requirements by altering the vitamin and mineral content and the individual proportions thereof with respect to local diets and/or the mineral content in the soil.

In a preferred embodiment of a composition according to the invention, iron particles in a separately microdispersed form is added to the composition, whereby stomach trouble may be avoided.

In the preferred embodiment of a composition according to the invention, the fish oil granulate makes up 60 % by weight, the vitamin portion 2,6 % and the mineral portion 14,5 %. By this proportion, a stable tablet may be provided with a particular high content of dry omega-3 granulate.

In a first embodiment of the invention, the mineral compounds include 8-12 % calcium, 3-4.5 % magnesium, 0.3-0.45% zinc, 0.3-0.5 % iron, 0.0030-0.0060 % iodine, 0.0010-0.0020 % selenium and 0.0010-0.0020 % chrome. Hereby, the proportion of the individual minerals in relation to the recommended daily doses is essentially the same.

Similarly, in the first embodiment, the vitamins in the vitamin content includes 0.1-0.2 % β-carotene, 0.03-0.05 % vitamin B_1, 0.04-0.06 % vitamin B_2, 0.4-0.5 % vitamin B_3, 0.1-0.25 % vitamin B_5, 0.04-0.07 % vitamin B_6, 0.02-0.03 % vitamin B_{12}, 0.004-0.008 % folic acid, 0.003-0.004 % biotin, 1-2 % vitamin C, 0.1-0.2 x 10^{-3} % vitamin D_3 and 0.2-0.4 % vitamin E. Hereby, the proportion of the individual minerals in relation to the recommended daily doses is essentially the same.

In the preferred embodiment of the invention, selenium aminochelate or a sodium selenium compound is used as the selenium compound. A selenium mineral supplement is anticipated to be beneficial in terms of achieving a positive outcome in the prevention of cancer and these selenium compositions are regarded as particularly active.

A nutritional composition according to the preferred embodiment is provided with natural fragrances that are added to the composition, such as vanilla and/or other natural substances. The nutritional composition may be made more attractive by flavouring a tablet and/or providing it with an aroma. In particular, the smell of the B-vitamins in the tablet container may hereby be removed. Other added natural substances could be ginger, ginseng, garlic or imidine.

Moreover, the tablet is provided with a coating encapsulating the composition in order to neutralise the overall smell and taste of the ingredients.

The composition of the individual substances in one tablet according to the invention is such that the individual amounts correspond to approx. 20-25 % of the recommended daily doses for the particular substance. Hereby, each tablet is kept adequately small in size whilst still containing the desired ingredients in the proportionally required amounts. A tablet with 50 % or more EPA/DHA is possible if the active components of the fish oil (EPA and DHA) are sufficiently concentrated.

A nutritional composition according to the invention is prepared as a tablet. Alternatively, other forms of nutritional supplements could be used. The tablet for use as a nutritional supplement to a diet on a regular basis, e.g. on a daily basis, comprises at least 50 mg of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Hereby, a reasonable proportion of the recommended daily amount of EPA and DHA may be obtained in a single tablet. The tablet including vitamin compounds comprises a selection of vitamins, mineral compounds and a selection of minerals, and fish oil granulate in dry pulverised form comprising EPA and DHA. The formation of a tablet with fish oil granulate together with other nutritional substances constitutes a complete nutritional supplement. This particular use of the fish oil granulate may improve the conventional nutritional supplements in the form of vitamin pills, since it is now possible to incorporate the active, health beneficial omega-3 fatty acids in an otherwise normal vitamin pill by the invention.

Detailed description of some preferred embodiments of the invention:

In the following, a detailed description of some preferred embodiments of a nutritional composition is presented.

Example 1

A nutritional composition according to the invention is produced in a basic tablet product. The content of the tablet is chosen in accordance with the RDA of the individual active minerals and vitamin substances of the ingredients and in such a way that a high proportional content of fish oil granulate is contained in the tablet. The contents are listed in table 1. The fish oil granulate comprises a relative high concentration of EPA and DHA in a proportion of 18:12. The proportion between EPA and DHA can be changed by preparing the fish oil granulate accordingly. E.g. it may be desirable in some cases to change the proportion to 15:15, i.e. increase the content of DHA. The amount of excipients is sufficient to produce the composition in a tablet form. The excipients could be e.g. starch, micro-crystalline cellulose, polyvidon and magnesium stearate.

Example 2

In example 2, an alteration on the basis of the basic product is made in order to direct the nutritional supplement towards the needs for sportsmen and the like. In comparison with the basic compound, the amounts of iodine and selenium are increased, just as the amounts of vitamins B_1, B_2, B_5 and B_6 are increased. The amount of EPA/DHA remains at about 60 % in the preferred composition. The amount of excipients is slightly reduced but still sufficient in amount to produce a tablet of the composition.

Example 3

Similar to example 2, in example 3 the basic product is also directed towards a specific category of users. The tablet in this example is intended for elderly people. Here, the amounts of calcium, magnesium, zinc, iron and chrome are increased. The amounts of β-carotene, pantothenic acid, vitamin B_{12}, folic acid, vitamin D_3 and E are also increased in comparison with the basic product. The amounts of EPA and

DHA are kept the same, but the excipients are reduced but not below a critical level for being able to produce the composition in a tablet form.

	Example 1		Example 2	Example 3
Product type:	Basic product		Tablet for Sportsmen	Tablet for Elderly
	Amount	pct. by weight of active substance	pct. by weight of active substance	pct. by weight of active substance
Minerals:				
Calcium carbonate	250 mg	10 %	10 %	11 %
Magnesium hydroxide	91.5 mg	3.75 %	3.75 %	4.125 %
Zinc oxide	4.7 mg	0.375 %	0.375 %	0.4125 %
Ferrofumarate	18.8 mg	0.35 %	0.475 %	0.475 %
Potassium iodide	491 µg	0.00375 %	0.00562 %	0.00562 %
Sodium Selenite	41.7 µg	0.00125 %	0.00125 %	0.00187 %
Chrome chloride	64 µg	0.00125 %	0.00187 %	0.00125 %
Vitamins:				
Betatab 20 % (β-carotene)	7.2 mg	0.12 %	0.12 %	0.18 %
Thiamine mononitrate (Vitamin B_1)	0.40 mg	0.035 %	0.0475 %	0.035 %
Riboflavin (Vitamin B_2)	0.44 mg	0.04 %	0.06 %	0.04 %
Niacin amide (Vitamin B_3)	4.5 mg	0.45 %	0.45 %	0.45 %
Calcium pantothenate (Vitamin B_5)	1.88 mg	0.15 %	0.225 %	0.225 %
Pyridoxine hydrochloride (Vitamin B_6)	0.57 mg	0.05 %	0.06 %	0.05 %
Vitamin B_{12}	0.28 mg	0.025 %	0.025 %	0.0375 %
Folic acid	62.5 µg	0.005 %	0.005 %	0.0075 %
Biotin	45 µg	0.00375 %	0.00375 %	0.00375 %
Ascorbic acid (Vitamin C)	17 mg	1.5 %	1.5 %	1.5 %
Vitamin D_3	0.55 mg	0.000125 %	0.000125 %	0.000187 %
Vitamin E	8.2 mg	0.25 %	0.25 %	0.375 %
Fish oil granulate (dry n-3)	600 mg	60 %	60 %	60 %
including EPA/DHA 18:12	50 mg			
Excipients and salts		22.86 %	22.56 %	21.05 %
Total	1226 mg	100 %	100 %	100 %

Table 1: Comparative table of the compositions in the examples.

The amounts of the substances may be altered without altering the proportion of the substance. Hereby, a tablet of a different size may be obtained, e.g. a tablet with ingredients that correspond to 25 % or 30 % of the recommended daily doses. In the table, the basic product is described with reference to a tablet of approx. 1200 mg. However, it is realised by the invention that a tablet of approx. 1000 mg may be preferable by some people. Besides the size of the tablet, the shape of the tablet may also be altered to suit the preferences of the consumers.

A tablet of the nutritional composition according to the invention is produced by weighing out the predetermined dosage of the ingredients and mixing these. In a tablet forming machine, the mixture is then compressed to a tablet in a predetermined form. The tablets may subsequently be coated by a suitable tablet coating equipment and with a chosen coating solution.

Throughout the process, quality checks of the tablets are made on various parameters, such as content, weight, variation in size, harness, friability and time of decay. Other additional checks may be carried out in order to establish the nutritional content of the finished product, etc.

In the process of manufacture, the handling of the fish oil granulate may be somewhat delicate. The fish oil granulate is stored in a nitrogen environment in order to shield the granulate from exposure to oxygen. Therefore, it is important to expedite the tablet forming process during the sub-processes of dosage, blending and mixture in order to avoid an exposure time of the fish oil granulate that may cause a deterioration of the granulate.

By the invention, it is realised that the nutritional composition may be altered within the scope of the accompanying claims, e.g. the composition may comprise other minerals and/or vitamins than those mentioned above, either instead of or as a supplement to one or more of the vitamins or minerals.

Patent Claims

1. A nutritional composition for dietary supplements comprising
(a) a vitamin portion including a selection of vitamins and derivatives thereof selected from a group of: β-carotene, vitamin B_1, vitamin B_2, vitamin B_3, vitamin B_5, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D_3, vitamin E, folic acid and biotin,
(b) a mineral portion selected from a group comprising compounds of calcium, magnesium, zinc, iron (ferrous compounds), iodine, selenium and chrome,
(c) at least 40 % by weight fish oil granulate containing polyunsaturated fatty acids including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

2. A nutritional composition according to claim 1, wherein iron particles in a separately microdispersed form are added to the composition.

3. A nutritional composition according to claim 1, wherein the fish oil granulate makes up 60 % by weight, the active substances of the vitamin portion make up approx. 2,6 % by weight and the active substances of the mineral portion make up approx.14,5 % by weight.

4. A nutritional composition according to any of claims 1 to 3, wherein the mineral compounds include 8-12 % calcium, 3-4.5 % magnesium, 0.3-0.45% zinc, 0.3-0.5 % iron, 0.0030-0.0060 % iodine, 0.0010-0.0020 % selenium and 0.0010-0.0020 % chrome.

5. A nutritional composition according to claims 1 to 4, wherein the vitamins in the vitamin content include 0.1-0.2 % β-carotene, 0.03-0.05 % vitamin B_1, 0.04-0.06 % vitamin B_2, 0.4-0.5 % vitamin B_3, 0.1-0.25 % vitamin B_5, 0.04-0.07 % vitamin B_6, 0.02-0.03 % vitamin B_{12}, 0.004-0.008 % folic acid, 0.003-0.004 % biotin, 1-2 % vitamin C, 0.1-0.2 x 10^{-3} % vitamin D_3 and 0.2-0.4 % vitamin E.

6. A nutritional composition according to any of claims 1 to 5, wherein the mineral portion comprises selenium aminochelate.

7. A nutritional composition according to claim 1, wherein natural fragrances are added to the composition.

8. A nutritional composition according to claim 7, wherein the at least one natural fragrance is vanilla.

9. A nutritional composition according to claim 7 or 8, wherein the natural fragrances are selected from a group of natural substances, such as ginger, ginseng, garlic and imidine.

10. A nutritional composition according to any of the preceding claims, wherein the nutritional composition is prepared as a tablet.

11. A nutritional composition according to claim 8, wherein the composition of the individual substances in one tablet is such that the individual amounts correspond to approx. 20-25 % of the recommended daily doses for the particular substance.

12. A tablet for use as a nutritional supplement to a diet on a regular basis, e.g. on a daily basis, including
vitamin compounds comprising a selection of vitamins,
mineral compounds comprising a selection of minerals, and
fish oil granulate in dry pulverised form comprising EPA and DHA.

13. A tablet for use as a nutritional supplement to a diet on a regular basis, e.g. on a daily basis, comprising at least 50 mg of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

INTERNATIONAL SEARCH REPORT

Int(onal Application No
PCT/DK 01/00296

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A23D9/05 A23L1/30 A23L1/302 A23L1/304

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A23D A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, FSTA, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 53777 A (CLAYTON DIANE ELIZABETH ;NOVARTIS NUTRITION AG (CH); LUSTENBERGER) 28 October 1999 (1999-10-28) claims 1-4,7; examples 1,3 page 2, paragraphs 3,5 -page 3, paragraph 1 page 4, paragraph 4 -page 5	12,13
A	page 6, paragraphs 2,6	1-11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
20 August 2001	28/08/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Tallgren, A

INTERNATIONAL SEARCH REPORT

Int nal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	claims 1,5,12,14; examples 3,4 page 1, line 8-11 page 5, line 8-19,30,31 page 6, line 6,7,18-20,29,30 page 7, line 37 -page 8, line 5 page 9, line 2-8 page 10 page 13, line 15-35 page 14, line 15-18	1-11
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A	FR 2 737 849 A (BOIRON) 21 February 1997 (1997-02-21) claims 1,4-6 page 1, line 21-32 page 3, line 27-31 page 5, line 4-25 page 6, line 13-20	1-13
A	FR 2 761 887 A (ASMAR ROLAND) 16 October 1998 (1998-10-16) claims 1-5 page 3, line 1-13	1-13

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Int[illegible]onal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

Int[illegible]onal Application No
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